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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,416

03/01/2004

Fred H. Burbank

SENOP-00106

1476

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08/04/2009

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EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,416	Applicant(s) BURBANK ET AL.	
	Examiner RENE TOWA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,40-46 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,40-46 and 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 13, 2008. Claims 1, 40-46 & 48-51 are pending. Claims 1, 40, 45 & 49 are amended. Claims 2-39 & 47 have been cancelled.

Terminal Disclaimer

2. The terminal disclaimer filed on April 10, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7,322,938 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **Claims 1, 40-45 & 49-50** are rejected under 35 U.S.C. 103(a) as being unpatentable over McGukin, Jr. (US 6,280,450) in view of Kieturakis (US 5,794,626), and further in view of Tihon et al. (US 5,415,656).

In regards to **claims 1, 40-45 & 49-50, McGukin, Jr.** discloses a biopsy instrument for retrieving body tissue, having a longitudinal axis and comprising:

- (a) an elongated shaft 20 having a longitudinal axis (see col. 6, lines 16-20);
- (b) a tissue penetrating distal end 65 adapted for tissue penetration (see col. 6, lines 50-52); and,
- (c) a distal shaft portion proximal to the distal end 65;

(d) an electrically powered cutting element or component (50, 55) coupled to the distal shaft portion which is longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the distal shaft portion, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see col. 6, lines 23-26; col. 7, lines 30-38),

wherein the tissue cutting component (50, 55) is longitudinally disposed on the distal shaft portion;

wherein the tissue cutting component (50, 55) is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen; and

(e) an encapsulation or tissue collection component (25, 30) configured to extend over the distal shaft portion to encapsulate the isolated tissue specimen and to secure the intact tissue specimen to the distal shaft portion to facilitate removal of the intact tissue specimen from a patient's body along with removal of the instrument (see col. 6, lines 34-38 & 45-49; col. 7, lines 39-47);

wherein the tissue collection component (25, 30) is fully capable of maintaining the encapsulated tissue specimen intact;

wherein both the cutting component (50, 55) and the tissue collection component (25, 30) are movable from a retracted position to an expanded position (see figs. 1-5).

McGukin, Jr. discloses an instrument, as described above, that teaches all the limitations of the claims except for an electrosurgical cutting element, an electrical conductor connected to said electrosurgical cutting element.

However, **Kieturakis** teaches that it is known to provide tissue cutting elements 15 with one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract; see figs. 2-3 & 5-8).

Moreover, **Tihon et al.** disclose an apparatus comprising an electrosurgical cutting element 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element; wherein the electrosurgical cutting element 1 may include one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the electrosurgical cutting element 1 is actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

In regards to **claims 1, 40, 45 & 49**, both McGukin, Jr. and Kieturakis teach biopsy instruments for retrieving body tissue (see respective abstracts); McGukin, Jr. further teaches a plurality of cauterizing cutting elements (see col. 5, lines 56-63; col. 6, lines 23-26), which are actuatable between a radially retracted position and a radially extended position (see col. 7, lines 30-38); Since Kieturakis teaches that that it is known to provide tissue cutting elements 15 with one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract; see figs. 2-3 & 5-8), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. with cutting elements having one end secured to a distal shaft portion and another end, which is movable with respect to a distal shaft portion as taught by Kieturakis in order to achieve biopsy instrument that is more rigid and thus facilitates tissue piercing.

Moreover, both McGukin, Jr. and Tihon et al. teach body excisional devices; McGukin, Jr. teaches cutting elements that are electrocauterizing (see col. 6, lines 23-25); since Tihon et al. teach an arrangement comprising a conductor for powering an electrosurgically powered cutter to excise a body tissue makes the cutting operation easier, more direct, and thus less traumatic, than cutting with an unpowered cutter (see col. 1, line 65 to col. 2, line 5), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr.

as modified by Kieturakis above with an electrical conductor as taught by Tihon et al. in order to power the electrosurgical cutter so as to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis. Moreover, it is known to provide instruments for encapsulating a specimen in vivo and withdrawing said specimen proximally therefrom (see figs. 1A-B, 3A-B and col. 7, lines 8-38 of US 5,730,726).

5. **Claims 46-48 & 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over McGukin, Jr. ('450) in view of Kieturakis ('626), Tihon et al. ('656), and further in view of Grayhack et al. (US 4,611,594).

McGukin, Jr. as modified by Kieturakis and Tihon et al. discloses an instrument, as described above, that fails to explicitly teach an instrument wherein the encapsulation component having a plurality of encapsulation elements which are radially extendable from a retracted position to an extension position.

However, **Grayhack et al.** teach that it is known to provide an encapsulation component having a plurality of encapsulation elements 16 which are radially extendable from a retracted position to an extension position; wherein the tissue encapsulation component 20 has a proximal end and a distal end, which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position;

wherein the tissue encapsulation component 20 is configured so that the distal end is fixed and the proximal end moves toward the distal end (see figs. 1-7; col. 3, lines 15-32; col. 4, lines 5-21).

In regards to **claims 46-47 & 51**, both McGukin, Jr. and Grayhack et al. teach instruments for encapsulating a specimen in vivo and withdrawing said specimen proximally therefrom; since McGukin, Jr. teaches an expandable aseptic shield to collectibly bag the target tissue mass detached from the patient for aseptic removal in an axial direction (see col. 2, lines 38-42) while Grayhack et al. teach that it is known to provide the encapsulation component with a plurality of encapsulation elements which are radially extendable from a retracted position to an extension position (see figs. 4-6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. as modified by Kieturakis and Tihon et al. with an encapsulation component having a plurality of encapsulation elements which are radially extendable from a retracted position to an extension position as taught by Grayhack et al. in order to collectibly bag the target tissue mass detached from the patient for aseptic removal in an axial direction.

In regards to **claim 48**, McGukin, Jr. teaches an electrically powered cutting element or component (50, 55) coupled to the distal shaft portion which is longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position relative to the distal shaft portion (see col. 6, lines 23-26; col. 7, lines 30-38) while Grayhack et al. teach that it is known to provide the encapsulation component with a plurality of encapsulation

elements which are radially extendable from a retracted position to an extension position (see figs. 4-6) , it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. as modified by Kieturakis, Tihon et al. and Grayhack et al. above to include a cutting element and an encapsulating element that expand and retract together as claimed in order to selectively expand and retract both the cutting element and the encapsulating component using a single actuator. Similarly, a single actuator provides the advantage that it may be manipulated with fewer maneuvers, thereby increasing automatism and reducing operational steps. Furthermore, it has previously been held that merely making integral is not patentable--See *in re Larson*, 340 F. 2d 965, 967, 144 USPQ 347, 349 (CCPA 1965); *In re Wolfe*, 251 F.2d 854, 855, 116 USPQ 443, 444 (CCPA 1958). It has also been previously held that merely making automatic is not patentable--See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 192, 194 (CCPA 1958).

Response to Arguments

6. Applicant's arguments filed April 10, 2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/790,416
Art Unit: 3736

Page 10

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736